

UK National Haemophilia Database Research Registry (UK-NHD-RR)

Patient Information Sheet- Adult

You are being invited to take part in research because you have a bleeding disorder and information about you is held on the UK National Haemophilia Database (NHD) to manage your blood condition. Please take time to read the following information carefully before you decide whether you want to be part of this research. Ask your doctor or specialist nurse at your Haemophilia Centre if there is anything that is not clear or if you would like to have more information. You may wish to discuss this with family or friends before deciding.

What is the National Haemophilia Database?

The UK NHD is a register of people in the UK with all types bleeding disorders. It was started in 1969 to improve the care of people with bleeding disorders. The database is held within the NHS and managed by the UK Haemophilia Centre Doctors' Organisation (UKHCDO) - a national group of doctors who look after people with bleeding disorders. Your local Haemophilia Centre collects information and sends it, within the NHS secure system, to the NHD to store and analyse. The NHD is mainly funded by the NHS but grants are also received from companies that make treatments for bleeding disorder.

What is the National Haemophilia Database – Research Registry?

The National Haemophilia Database Research Registry (NHD-RR) is a subsection of the NHD that holds information about patients for the purpose of research. It is data collected routinely, and on occasions, additional data is collected as need from Haemophilia centres about your bleeding disorder. The management of the database, and any research that is done using the information that it holds, is overseen by a committee that includes representatives of people with bleeding disorders and The UK Haemophilia Society.

Why am I being asked whether I agree to my information being used for research?

In addition to using your information to help with your day to day care and to plan NHS services, we would like to ask your permission to use your data for research. We will only use your personal information for research if you agree to this and sign a consent form. We hope that this research will help us to understand bleeding disorders better and to improve the care of people with bleeding disorders. Bleeding disorders are rare conditions and by combining information from many people across the UK over a long period of time we are able to get a much better understanding of these disorders and their treatment.

What types of research does the National Haemophilia Database do?

The NHD does observational research. This means that any treatment you receive is agreed between you and your haemophilia Centre, and NHD observes (looks at) what happens. UKHCDO and NHD do not undertake any clinical trials and whether you take part in a clinical trial is entirely between you and your Haemophilia Centre.

The NHD undertakes research into the number of people with bleeding disorders in the UK, the treatment they receive and how well this treatment works. Research is done on the number of bleeds and people have and the treatment that is given at home by looking at Haemtrack records. The causes and consequences of complications of bleeding disorders, such as joint or muscle disorders, inhibitors and infections caused by blood products are also studied. The chance of having any of these complications is related to the severity and type of the disorder and the treatment you have received over your life time. NHD only does research that is related to your bleeding disorder.

The NHD also looks into life expectancy and causes of death of people with bleeding disorders. Other areas of research include the interaction between your bleeding disorder and other medical conditions that people with bleeding disorders can develop like any other person. The NHD combines all the information it holds, including joint scores, genetic tests and information from Haemtrack to answer these questions.

As part of the research of the NHD, reports are prepared for companies that make treatments for bleeding disorders. These reports help the companies to plan how much treatment is needed for people with bleeding disorders in the UK, to see how well their treatments are working and whether any complications have happened. In these reports it is not possible to identify you as an individual. The information released in these reports is agreed by a committee that includes patient representatives. The companies pay for these reports and this helps to fund the NHD.

In some cases information held in the NHD is linked with information held in another database within the NHS to allow a better understanding of bleeding disorders and their treatment. This means that your NHS number is used to link information in the NHD with other information held by the NHS. Each time this is done an application is made to the Health Research Authority to ensure that we are using your information appropriately.

What does the National Haemophilia Database do with my information outside of research?

The information is collected so that people with bleeding disorders continue to receive safe, high quality, care and to improve that care. Your Haemophilia Centre uses the information held by NHD to help look after you. The information is also used to make sure that the treatment and care of patients with bleeding disorders is adequately funded and planned by the NHS and to help new treatments to be introduced as soon as possible. Every year an annual report is prepared that shows the information collected by the NHD. You can read this report at www.UKHCDO.org.

Who is sponsoring this NHD-RR?

Manchester University NHS Foundation Trust (MFT) is the sponsor of the NHD-Research Registry in the UK. NHD and MFT will be using information from your medical records and information held by the NHD to undertake research and will act as the data controller for this purpose. This means that MFT and NHD are responsible for looking after your information and using it properly.

A list of the information that the NHD collects routinely is available at <http://www.ukhcd.org/patient-information/>. The information held by the NHD is kept indefinitely so we can look for any changes in the number of people with bleeding disorders and the effect of treatment trends over time. Additional information as above.

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Who can access the information from NHD?

The NHD may also do studies with other bleeding disorder registries or research groups from around the world. In this case information from the UK is combined with similar information from other countries. If information is released to any researcher outside of the NHD you will be identified by a code only and none of your personal information will be released. External researchers could be from the UK, Europe or rest of the world.

Information is only released from the NHD after this has been agreed by a committee that includes people with bleeding disorders.

What is done with the results of research done by the National Haemophilia Database?

The results of the research may be published in medical journals or presented at national and international meetings to help clinicians around the world have a better understanding of bleeding disorders and their treatment. Reports are also sent to companies that make treatments for bleeding disorders.

It will not be possible to identify you in any of these publications, presentations or reports because all reports are anonymized. Information that can be used to identify you such as your name, date of birth or NHS number is never released by the NHD to researchers either in the UK or outside. This information is only released to your haemophilia centre.

Do I have to agree for my information to be used for research?

No you not have to agree. If you decide that you do not want your information to be used for research this will not affect the treatment or care you receive in any way, now or in the future. If you decide not to agree for your information to be used for research your Haemophilia Centre will continue to use your information to help to look after you on a day to day basis and your information will be used to help plan health care within the NHS.

What will happen to me if I take part?

You will be asked to sign a consent form giving permission for the medical information held on you by the National Haemophilia Database to be looked at for research projects and reports. You will not need to do anything else. There will be no additional blood tests or visits to the hospital.

What are the possible disadvantages, risks and benefits of taking part?

If you agree to take part we do not anticipate any disadvantages to you. We cannot promise that any research will help you directly, but it may help other people with bleeding disorders in the future.

What if I change my mind?

Your participation is entirely voluntary and you are free to withdraw permission (change your mind) to use your information for research at any time and without giving any reason. This will not affect your medical care or legal rights in any way. If you decide to withdraw we will not use any information collected on you for research studies in the future. The information held on you by the NHD will continue to be used by your Haemophilia Centre to help with your routine care and by the NHS to plan services.

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Will my taking part in this study be kept confidential?

All information which is collected by the NHD about you is kept strictly confidential whether or not you agree to your information being used for research. If you agree to allow your information to be used for research, your information will be handled in accordance with the Data Protection Act 2018 and all other laws.

Representatives of regulatory authorities or the ethics committee will be allowed to see your information as required to ensure the research is being properly conducted and that the data collected is accurate. Your privacy will be respected at all times.

You have the right to ask to see the data that has been collected about you and if you think anything is incorrect, to have it corrected.

Who has reviewed the study?

This research programme has been reviewed by North West - Haydock Research Ethics Committee, and the reference number is 19/NW/0009. UKHCDO and NHD send a report to the ethics committee each year to say what research has been done with the information held by the NHD. This report will be published on the UKHCDO website.

What happens if there is a problem?

We would not expect you to suffer any harm or injury from the use of your information held by the NHD for research. If you are harmed in any way there is no special compensation arrangement. If you are harmed due to someone's negligence then you may have grounds for legal action, but you may have to pay your legal cost. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this consent process, the normal National Health Service Complaints mechanism is available to you. If you have any concerns or as an initial point of contact if you have a complaint, please contact the Patient Advice and Liaison Service (PALS) at the address given below;

PALS office:

Telephone: 0161 276 8686

Address: PALS, The Chief Executive, MFT, Headquarters, Cobbett House, Oxford Road, Manchester, M13 9WL

or UKHCDO on 0161 277 7991 or email: support@ukhcdo.org

Contact for further information?

If you require any further information please do not hesitate to discuss this information sheet with any of the nurses or doctors looking after you. If you would like to discuss the information sheet with an independent group you can contact the UK Haemophilia Society on info@haemophilia.org.uk.

Thank you for taking the time to read this leaflet.

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